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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,467	07/23/2003	Peter Berrang	8006P22	7442
24320	7590	12/11/2006		
Paul Smith Intellectual Property Law 330-1508 West Broadway Vancouver, BC V6J1W8 CANADA			EXAMINER HOPKINS, CHRISTINE D	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,467

Applicant(s)

BERRANG ET AL.

Examiner

Christine D. Hopkins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8 January 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Inventorship

1. In view of the papers filed September 22, 2006, the inventorship in this nonprovisional application has been changed by the deletion of Alan Lupin.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 3 and 22-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. At line 1 of claim 3, the claimed recitation of a use ("the use of the hearing device of claim 1 as a tinnitus masker"), without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). At line 1 of claims 22-25, the claims recite the hearing device "in place in an inner ear." The positive recitation of an organ or tissue deems the claim non-statutory.

Furthermore, at line 5 of claims 22-25, the same applies by positively reciting the positioning of the vibrational assembly away from the superior or horizontal canal.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-3, 9, 22-25, 27 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At line 3 of claims 2 and 3, it is uncertain whether or not the housing contains a battery since it is preceded by the phrase "and/or." Further, claim 3 provides for the use of the hearing device as a tinnitus masker, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. At lines 2-3 of claim 9, it is uncertain whether or not the bonding layers are physically joined by the bending of the etched metal clip, or the bonding layers are actually formed by bending an etched metal clip. At line 2 of claim 30, it is uncertain whether or not the housing contains grooves since it is preceded by the phrase "and/or."
6. Claims 22-25 at line 4 recite the limitation "the base of said vibrational assembly." There is insufficient antecedent basis for this limitation in the claims.

Claim 27 at line 1 recites the limitation "the base of said housing." There is insufficient antecedent basis for this limitation in the claim.

Claim 30 at lines 2-3 recites the limitations "along the length of the outside cylindrical wall of said housing." There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7, 9-11, 15-16, 18-20, and 22-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (U.S. Patent No. 6,005,955). Kroll et al. (hereinafter Kroll) disclose an electromechanical transducer for an implantable hearing aid. Regarding claims 1 and 5, Kroll teaches a carrier **105**, or "housing" that is hermetically sealed and contains the "vibrational assembly" of transducer elements and inertial mass (col. 8, lines 65-67 - col. 9, lines 1-5), adapted to be implanted near the semicircular canal (col. 6, lines 47-54).

With reference to claims 2-4, Kroll further discloses the device having a microphone, "electronics" for producing electrical signals, and a drive coil (col. 5, lines 36-46). An array of electrodes aids in stimulating the nerve fibers, ultimately transmitting an impulse to the brain that is interpreted as sound (col. 5, lines 5-17).

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Regarding claims 6 and 10, the transducers, or “controllable vibrating elements” may be composed of a plurality of stacked piezoelectric transducers, or piezoceramic components, and at least one inertial mass (col. 1, lines 51-60). Likewise, regarding claim 11, electromagnetic transducers may be utilized for affecting mechanical vibrations (col. 5, lines 32-35). In view of claim 7, the piezoelectric layers, stacked according to opposing polarity, may be bonded together (col. 6, lines 7-14) and may be “disk-shaped” or cylindrical (col. 12, lines 46-51).

Regarding claim 15, the “vibrating element,” or transducer, consists of two elements **100A-B**, of opposite polarity whereby element transducer **100A** will expand longitudinally in response to a received electric signal and consequently, element transducer **100B** will contract longitudinally, thus creating a “bimorph” (col. 8, lines 53-56).

In view of claim 16, the transducer may be made of a polyvinylidene fluoride (col. 13, lines 32-34), having a low melting point, thus capable of undergoing a volume change in response to localized heating.

Regarding claims 18-19 and 28, Kroll teaches a carrier, or “housing” having a “top” (defined as the side of the carrier connected to the electronics unit via lead wires). The carrier may be constructed of titanium (col. 8, lines 65-67), such an element having flexible properties. The “top” may be connected to a stack of piezoelectric crystals such as shown in Fig. 11A. Stacked transducers **140, 145** contain the piezoelectric elements. They are interconnected via lead wires **85, 90** that feed through and connect to, the “flexible top” (col. 10, lines 59-67 - col. 11, lines 1-16).

Referring to claim 20, the "vibrating element," or transducer, consists of two piezoelectric elements **100A-B**, of opposite polarity, whereby element transducer **100A** will expand longitudinally in response to a received electric signal and consequently, element transducer **100B** will contract longitudinally, thus creating a "bimorph" (col. 8, lines 27-37 and 53-56). The piezoelectric elements **100A-B** are connected to the "flexible top" via lead wires **85, 90** (see Fig. 7).

Regarding claims 22-25, and in light of the non-statutory subject matter, Kroll teaches a "vibrational assembly" incorporating a piezoelectric element, and an inertial mass **80**, the inertial mass having a displacement, or "vibrational axis of motion" orthogonal, or perpendicular to, the plane of the superior semicircular canal (col. 8, lines 27-37). Furthermore, regarding claims 24-25, Kroll notes that the piezoelectric effect may be applied in another direction other than perpendicular to the surface, hence the piezoelectric element may be re-arranged in such a fashion that its axis of motion is substantially perpendicular to the "horizontal semicircular canal."

In view of claim 26, the "vibrational assembly," having the vibrating element and inertial mass **80**, results in vibration of the carrier **105**, or "housing" via the vibration of the inertial mass (col. 8, lines 62-64).

Regarding claim 27, and in light of the indefinite nature surrounding "the base" of the housing, "the base" is connected to a plurality of lead wires **85, 90** and defined as the side of the carrier connected to the lead wires (see Fig. 7) where the lead wires are disposed through the housing "base."

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9. Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kroll et al. (U.S. Patent No. 6,005,955). Kroll discloses that the piezoelectric elements, joined by bonding layers as disclosed in claim 7, are further joined by lead wires **85, 90** (an electrically conductive link) connecting an electronics unit to each of the piezoelectric elements (see Fig. 11A), but is silent as to a method of forming the bonding layers. The claimed phrase "by bending an etched metal clip to form the bonding layers" is being treated as a product by process limitation; that is the layers are bonded by bending an etched metal clip. As set forth in MPEP 2113, product by process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. Thus, even though Kroll is silent as to the process used to join the layers, it appears that the product of Kroll would be the same or similar as that claimed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Lesinski et al. (U.S. Patent No. 5,772,575). Kroll discloses the invention as claimed, see rejection supra; however Kroll fails to teach conductive bonding layers extending beyond the outer circumference of the

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piezoelectric elements. Lesinski et al. (hereinafter Lesinski) teaches a hearing device to be implanted within a subject's ear. Regarding claim 8, Lesinski discloses that conductive bonding layers (**45a** in Fig. 3) extends beyond the piezoelectric element, or transducer **45** (col. 11, lines 43-52), thus enabling it to serve as a "contact pad."

Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have incorporated a conductive layer, as taught by Lesinski, extending beyond a transducer, similar to that disclosed by Kroll, for providing an electrical contact for a particular element such as a lead wire or electrode.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Cross et al. (U.S. Pub. No. 2004/0234086).

Kroll discloses the invention as claimed, see rejection supra; however Kroll fails to teach a magnetostrictive component of the vibrating element, or transducer. Cross et al. (hereinafter Cross) disclose a communication device that may be used to aid those with impaired hearing. Regarding claim 12, Cross teaches a magnetostrictive transducer for converting electrical audio signals into sound waves [0001]. Furthermore, Cross teaches that the device may be enclosed within a hermetically sealed housing as disclosed by Kroll and the instant application. Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have incorporated a magnetostrictive component as taught by Cross to a transducer such as that taught by Kroll for converting electrical signals to sounds interpreted by the brain for enabling one with an impairment to hear.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Zinserling (U.S. Patent No. 6,351,541). Kroll discloses the invention as claimed, see rejection supra; however Kroll fails to teach an electrostatic component of the vibrating element, or transducer. Zinserling teaches an electrostatic transducer for use in a hearing aid. Regarding claim 13, Zinserling discloses an electrostatic transducer arranged within a housing of an ear piece in such a fashion so as to minimize resonance (col. 2, lines 40-47). Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have incorporated an electrostatic component as taught by Zinserling to a transducer such as that taught by Kroll for minimizing resonance in the hearing device and improving the quality of sound transmitted to the user.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Schubert et al. (U.S. Patent No. 6,822,929). Kroll discloses the invention as claimed, see rejection supra; however Kroll fails to teach an electrothermal component of the vibrating element, or transducer. Schubert et al. (hereinafter Schubert) teach a device having a microphone for detecting a sound signal and generating an electrical signal. Regarding claim 14, Schubert teaches an actuator mechanism, or "vibrating element" having an electrothermal, electrostatic, magnetic or piezoelectric component for exciting a vibration (col. 5, lines 29-35), for use with a microelectronic system such as the case for a hearing device. Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have incorporated an electrothermal component as taught by Schubert to a transducer as

suggested by Kroll for imparting a signal subsequently converted to a sound for improving the hearing of an impaired user.

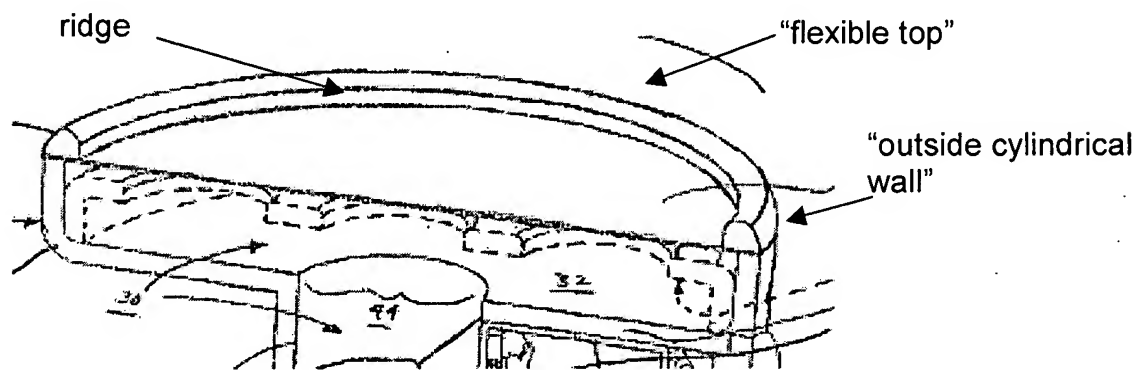
15. Claims 17 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Maynard (U.S. Patent No. 6,408,496). Kroll discloses the invention as claimed, see rejection supra; however Kroll fails to teach a particular material used to construct the inertial mass. Maynard teaches the fabrication of a vibrational transducer suited for use in a hearing mechanism. Regarding claim 17, Maynard discloses an inertial mass composed of a dense metal such as gold or platinum (col. 6, lines 4-7). Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have made an inertial mass such as that taught by Kroll of a material such as gold for providing a metallic, dense element that will vibrate in response to a vibration received from a transducer within a hearing device.

Regarding claims 31-32, the housing may comprise a biocompatible coating, at least in part of silicon. Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have constructed a housing as taught by Kroll to be coated with a biocompatible material such as that disclosed by Miller to implant a hearing device into a particular orientation in a human ear and aid compatibility with human tissue.

16. Claims 21 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Miller (U.S. Pub. No. 2002/0071585). Kroll discloses the invention as claimed, see rejection supra; however,

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Kroll fails to teach a flexible top having one or more ridges in the form of concentric rings impressed into the top. Miller teaches an implantable hearing device having a microphone within a housing. Regarding claims 21 and 29-30, and in view of the indefinite nature of "the outside cylindrical wall" of claim 30, Miller discloses a diaphragm or "flexible top" **52** made of titanium, as in the instant application, and disk-shaped (defining a "concentric ring") with a ridge (see depiction below), having a thickness of 10 to 20 microns [0029].



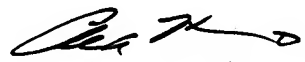
Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have constructed a flexible top having the dimensions such as that taught by Miller into a hearing device similar to that disclosed by Kroll to provide a flexible basis with a ring arrangement for a hearing device to be implanted into a particular orientation in a human ear and aid osseointegration of the device within the ear.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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